REMARKS

Claims 1-7 and 9-11 are pending. Claim 8 was previously canceled. Claims 12-47 have been canceled because they are in non-elected groups. Applicants expressly reserve the right to prosecute the canceled subject matter in other related applications.

Specification

The Examiner has requested that the trademarks Qiaquick, gluta Max-I, Fmax, Ficoll-Paque, RNeasy Midi, SuperscriptII, Pellet Paint, ElectroMax, Nucleobond-giga, Super Broth, and lipofectamine etc. be capitalized wherever they appear and be accompanied by the generic terminology.

Please delete ~~Cytosensor~~ and insert at page 53, line 7,—microphysiometer CYTOSENSOR®-- .

Please delete ~~Qiaquick~~ and insert at page 72, lines 13, 22, 29; page 73, line 3; page 75, lines 19, 24; page 104, line 28; page 114, line 20, and --PCR purification reagents QIAQUICK®--.

Please delete ~~Qiagen Maxi Prep Kit~~ and insert at page 74, line 3; page 91, line 17; page 120, line 30–QIAGEN® Maxi Prep Kit--.

Please delete ~~Geneticin™~~ at page 74, line 13 and insert --G-418 Sulfate antibiotic GENETICIN™--.

Please delete ~~alamarblue~~ and insert at page 74, lines 18, 19; page 76, lines 12 , 21; page 77, line 4; page 78, line 27; page 110, lines 6, 7-- ALAMAR BLUE™--.

Please delete ~~gluta Max-I~~ and insert at page 74, line 1, -- cell media supplement L-GLUTAMAX-1® --.

Please delete ~~alamar blue~~ and insert at page 75, line 1; page 77, line 15; page 84, line 18; page 100, line 14; page 110, line 2; page 113, line 19; page 179, lines 6, 16, 30; page 180, lines 10, 11 --cell growth and cytotoxicity indicator dye ALAMAR BLUE™--.

Please delete ~~Fmax~~ and insert at page 75, line 4; page 77, line 17, page 100, line 15 --EMAX® microplate reader--.

Please delete ~~Ficoll Paque~~ and insert at page 76, line 28; page 163, line 23 --tissue culture density media FICOLL-PAQUE PLUS™--.

Please delete ~~RNeasy Midi~~ and insert at page 80, line 27 --total RNA isolation kit RNEASY® MIDI--.

Please delete ~~"MPG mRNA purification kit"~~ and insert at page 80, line 29 --MPG®mRNA purification kit--.

Please delete ~~SuperscriptII~~ and insert at page 81, lines 10, 15--reverse transcriptase SUPERSCRIPT®II--.

Please delete ~~Pellet Paint~~ and insert at page 82, lines 23, 30 --Non-fluorescent visible DNA co-precipitant PELLET PAINT®--

Please delete ~~DH10b-ElectroMax~~ and insert at page 73, line 11; page 76, line 1, page 84, line 3; page 86, line 30; page 114; page 29; --*E.coli* DH10b™ competent cells ELECTROMAX™ --.

Please delete ~~Nucleobond giga~~ and insert at page 84, line 25 –an anion exchange matrix plasmid purification method NUCLEOTBOND®--.

Please delete ~~Super Broth II~~ and insert at page 85, lines 4, 9; page 87, line 2; page 136, lines 1, 3 21, 23; page 173, lines 24, 27 --enriched culture medium SUPER BROTH® II--.

Please delete ~~Qiaprep™~~ and insert at page 85, line 20 --QIAPREP®--.

Please delete ~~Lipofectamine~~ and insert at page 86, lines 3, 4, 6, 8, 9, 11; page 87, line 9; page 93, lines 12, 15, 16, 18, 19, 22, page 101; lines 4, 18; page 114, line 29; page 121, lines 9, 12, 13, 15, 16, 19; page 124, line 19 --transfection reagent LIPOFECTAMINE™--.

Please delete ~~QiaexII™~~and insert at page 88, line 20; page 108, line 24 --QIAEXII®--.

Please delete ~~Vectashield~~ and insert at page 102, line 16 --VECTASHIELD®--

Please delete ~~"RoboCycler Gradient 96"~~ and insert at page 102, line 30 --ROBOCYCLER®Gradient 96--.

Please delete ~~"RediLoad"~~ and insert at page 103, line 3 --REDILOAD™ agarose gel loading buffer--.

Please delete ~~Advantage~~ and insert at page 103, line 4--ADVANTAGE®--

Please delete ~~Marathon~~ and insert at page 104, lines 1, 2, 3, 5, 12, 13 -- MARATHON®--

Please delete ~~Prime-Itr RmT~~ and insert at page 107, line 9 –PRIME-IT®--

Please delete ~~ExpressHyb™~~ and insert at page 107, line 11; page 184, line 11 –EXPRESSHYB™--.

Please delete ~~Nycoprep~~ and insert at page 112, lines 28, 30; page 155, line 21 --NYCOPREP®--

Please delete ~~DH5α Library Efficiency~~ and insert at page 128, lines 12-13 –DH5α LIBRARY EFFICIENCY®--

Please delete ~~DH10Bac Max Efficiency~~ and insert at page 132, lines 25-26 --MAX EFFICIENCY® DH5B™--.

Please delete ~~FACSCalibur~~ and insert at page 146, line 12; page 156, line 13; page 187, line 21 --flow cytometer FACSCALIBUR™--.

Please delete ~~Cell-Dyn 3500~~ and insert at page 146, line 22; page 182, line 27 –CELL-DYN® 3500--.

Please delete ~~Instat~~ and insert at page 147 lines 9, 29 --INSTAT™--.

Please delete ~~WinNonLin~~ and insert at page 152, line 16 -- WINNONLIN®--.

Please delete ~~Dynabeads~~ and insert at page 156, line 21; page 157, line 5 -- DYNABEADS®--

Please delete ~~RNeasy Miniprep~~ and insert at page 166, line 4 -- total RNA isolation kit RNEASY® MINI--.

Please delete ~~pBluescript II SK (+)~~ and insert at page 184, line 20 – phagemid kit pBLUESCRIPT® II SK(+)--

The Examiner objected to the disclosure because it contains an embedded hyperlink and/or other form of browser-executable code (see p. 102).

Please amend page 102, lines 26-27 to delete:

~~A publicly available WWW server (http://shgc-www.standford.edu) allows chromosomal localization of markers~~.

Please amend page 103, line 17 to delete:

~~WWW server: http://cedar.genetics.soton.ac.uk/public_html/~~

Rejections Under 35 U.S.C. §112

The examiner rejected claims 1-7 and 9-11 under 35 U.S.C. §112, first paragraph alleging that the specification, while being enabling for polypeptide of SEQ ID NO:2, allegedly does not reasonably provide enablement for all possible variants contemplated by the applicant, including those at are at least 90% or 95% identical to fragments of SEQ ID NO: 2 . The claims also recite the phrases "a sequence of amino acid" and thus, are broadly interpreted by the examiner as reading upon: (i) protein variants with any number of deletions, substitutions, or additions and (ii) fragments of SEQ ID NO:2, including sequences only 6 amino acids in length .

The examiner also rejected claims 1-7 and 9-11 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants respectfully traverse the rejections. In making these rejections, the examiner has unreasonably interpreted the claims broadly as reading upon any and all DNA and protein variants with any number of deletions, substitutions or additions, and upon all fragments of SEQ ID NO: 2 provided those variants are at least 90% or 95% identical to SEQ ID NO: 2 and include sequences only 6 amino acids in length. Relying on the same broad interpretation, the examiner also rejected the same claims for failure to meet the written description requirement under 35 USC §112, first paragraph.

The USPTO has clearly decided to change the interpretation of previously accepted claim language as evidenced by the double patenting rejection set forth in paragraph 8a of the instant Office Action. In this nonstatutory obviousness-type double patenting rejection some of the claims rejected under 35 USC § 112, first paragraph (claims 1-4 and 6) are rejected over previously issued claims 1-4 and 12 of U.S. Patent No. 6,307,024, where the now rejected language was then deemed patentable. In the Office Action, the only explanation provided to applicants of why previously accepted

claim language is not longer acceptable is that the claims are now broadly being interpreted.

The USPTO must employ the "broadest reasonable interpretation" standard for examining claims where such broadest reasonable interpretation must be "consistent with the specification". (See, MPEP 2111). The key word in this standard is "reasonable". Applicants contend that the interpretation of the claims to encompass any number of variants and any fragment of 6 or more amino acid residues that is at least 90% or 95% identical to SEQ ID NO: 2 is not reasonable because it is not consistent with the use in the specification, that which was understood by those skilled in art, and the history of prosecution in family of patents from which this application arises.

The USPTO is unreasonably ignoring the recited sequence defined within the claim when interpreting the claim as reading upon "protein variants with any number of deletions, substitutions, or additions; and fragments of SEQ ID NO: 2, including sequences only 6 amino acids in length." The claims recite specific sequences, e.g. sequences with at least 90% or 95% identity residues 32-162, 32-148, or 41-141 of SEQ ID NO: 2. This plain language, previously understood to mean what it says, the polypeptides will have at least 90% or 95% identity to a sequence comprising amino acid residues 32-162, 32-148, 41-148 of SEQ ID NO: 2, has been essentially rewritten to mean: **a polypeptide of at least 90% (or 95%) identity to any six amino acids present in SEQ ID NO: 2.**

One consequence of interpreting the claims in this manner is that the longer the specified sequence is, the broader the claim actually is, which is not how claims are generally interpreted, nor how the claims were intended to be interpreted.

Moreover, Applicants contend that the USPTO's new interpretation of the contested claim language cannot be the "broadest reasonable interpretation consistent with the specification" and is consequently unreasonable because its interpretation manifestly ignores the context of the specification. The rejections under 35 USC §112, first paragraph, are based on the assertion the specification does not describe (written description) nor enable (enablement) variants, fragments or derivative polypeptides of SEQ ID NO:2. The examiner maintains that the specification merely invites one skilled

in the art to further experiment because identification of the active site or binding site may not be sufficient to maintain activity. Applicants respectfully maintain that the examiner is incorrect in the assertions that applicants did not (1) provide teachings that provide guidance beyond just identifying a binding site, (2) attribute any function to the claimed protein, and (3) provide teachings for how to test for that function. The instant claims are directed to, and the specification discloses, functional polypeptides with at least 90% (or 95%) identity to the mature protein (residues 32-162) and the complete helical region (residues 41-148). Additional fragments within SEQ ID NO:2, such as helix A defined as residues 41-56, helix B as residues 69-84, helix C as residues 92-105, and helix D as residues 135-148 of SEQ ID NO: 2 (See, table 1, page 13) are disclosed because these structural regions are known to be highly conserved within this cytokine family providing structural characterization that guide the skilled artisian to make changes within the sequence that maintain functional aspects of the protein. The specification discloses that detailed mutational analysis has been performed within this family and critical residues, not only the residues identified as binding residues, but also those involved in the helical and loop structures, have been identified (pages 10-13). Based on these studies, the effects of substitutions, deletions and additions are not merely speculation. Moreover, the biological function of polypeptides of the present invention are clearly described in the specification and include: binding of the polypeptide to its binding partners (page 32, line 10), such as anti-zalpha11 ligand antibody or cognate receptor, a proliferative or differentiating activity; specialized cell functions (for example on page 34, lines 6-10). Numerous examples and assays describing *in vivo* and *in vitro* biological activites of the zalpha11 Ligand (a.k.a. IL-21) polypeptides of the present invention are provided. Explemary proteins are made and tested using the teachings and assays disclosed therein. Applicants assert that the examiner is incorrect in assuming that a skilled artisian would not know what function to test for. The specification identifies the cognate receptor, provides assays to test binding, including assays that measure biological activity, and therefore testing is routine experimentation. Applicants clearly describe the fragments and variants both structurally and functionally. Throughout, the specification describes and enables fragments of SEQ ID NO:2, sequences of varying

lengths, and structural changes that can be made without compromising the function of the protein.

While the specification includes a generic description that polypeptides "of less than about 10 amino acid residues are commonly referred to as 'peptides'." (page 6, lines 24-25), the invention must be viewed in the context of the entire specification and claims. When viewed in this manner, it is clear that when the intent was to describe fragments, shorter sequences are defined as such. For example, when polypeptides are intended to encompass functional fragments , e.g., at least helix A, B, C, or D, or mature polypeptide sequences of SEQ ID NO:2, that information is clearly conveyed. When the intent is to cover a longer sequence, that sequence is recited. The specification offers clear description and enablement of specific fragments and variant sequences recited in the claims, and such sequences are identified based on scientific evidence and reasoning. Given a reasonable interpretation of the language consistent with the specification, claims directed to those specific sequences are clearly defined. The instant specification provides clear written support as well as sufficient disclosure and guidance for one of skill in the art to make and use the polypeptides of the present invention without undue experimentation, as required by 35 USC §112, first paragraph. Upon reading the specification and claims, those ordinarily skilled in the art would recognize that any claimed polypeptides are biologically functional as stated within the specification (e.g., page 35, lines 5-6). Consequently, it would be unreasonable for a skilled artisan, or the USPTO, to read "a sequence of amino acid [residues] as shown in SEQ ID NO: 2 from residue 32 to residue 162", or residues 41-148 or residues 32-148, to include fragments as small as six amino acids as an element of the claimed invention.

To summarize applicants' position, the Office has adopted an unreasonable and overly broad interpretation for claims to a genus of polypeptides with at least 90% or 95% identity to a specific sequence of SEQ ID NO: 2. The Office has interpreted the claims to cover all polypeptides of at least six amino acids, with any substitution, deletion or addition. Applicants traverse the rejection of the claims because it based on an overly broad claim scope which has disregarded applicants' teachings, the actual data presented, and what would be considered a reasonable interpretation of the

claim language. Applicants respectfully request the rejection be withdrawn and the claims be allowed.

Double Patenting

The Examiner rejected claims 1-4 and 6 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 12 of U.S. Patent No. 6,307,024. Enclosed herewith is an appropriate Terminal Disclaimer, which Applicant believes overcomes the obviousness-type double patenting rejection. This Terminal Disclaimer is filed solely for its statutory function of removing the rejection of double patenting and is not to be regarded as an acquiescence in the merits of the rejection. Quad Environmental Technologies Corp. v. Union Sanitary District, 946 F.2d 870, 874, 20 USPQ2d 1392, 1394-95 (Fed. Cir. 1991).

The Examiner provisionally rejected claims 1-7 and 9-11 under 35 U.S.C. §101 as claiming the same invention as that of claims 1-7 and 9-11 of copending Application No. 11/551,807.

Upon notification by the examiner that claims 1-7 and 9-11 of the instant application are allowable, cancelation of the claims in the co-pending application will be made to overcome the rejection under 35 USC § 101 as claiming the same invention and notice sent to the examiner.

Reconsideration and withdrawal of the rejections in view of the above amendments and following remarks are respectfully requested. Claims 8 and 12-47 having been canceled, the pending claims of the instant application are claims 1-7 and 9-11.

No new matter has been added.

Applicants reserve the right to prosecute claims to cancelled subject matter in one or more continuing applications.

Conclusion

In light of the above amendments and remarks, reconsideration and withdrawal of the rejections are respectfully requested. It is, thus, respectfully requested that claims 1-7 and 9-11 are in condition for allowance and notification to that effect is respectfully requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 442-6672.

Respectfully Submitted,

Deborah A. Sawislak
Registration No. 37,438

Enclosures:

Amendment Fee Transmittal
Petition to Extend Time
Terminal Disclaimer

Customer No. 10117
ZymoGenetics, Inc.
1201 Eastlake Avenue East
Seattle, WA 98102